



**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to L-theanine from *Camellia sinensis* (L.) Kuntze (tea) and improvement of cognitive function (ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005), alleviation of psychological stress (ID 1598, 1601), maintenance of normal sleep (ID 1222, 1737, 2004) and reduction of menstrual discomfort (ID 1599) pursuant to Article 13(1) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to L-theanine from *Camellia sinensis* (L.) Kuntze (tea) and improvement of cognitive function (ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005), alleviation of psychological stress (ID 1598, 1601), maintenance of normal sleep (ID 1222, 1737, 2004) and reduction of menstrual discomfort (ID 1599) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to L-theanine from *Camellia sinensis* (L.) Kuntze (tea) and improvement of cognitive function, alleviation of psychological stress, maintenance of normal sleep and reduction of menstrual discomfort. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food/constituents that are the subject of the health claims are *Camellia sinensis* (L.) Kuntze (tea) and L-theanine. The Panel considers that while *Camellia sinensis* (L.) Kuntze (tea) is not sufficiently characterised in relation to the claimed effects, L-theanine from *Camellia sinensis* (L.) Kuntze (tea) is sufficiently characterised.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1843, EFSA-Q-2008-1960, EFSA-Q-2008-2334, EFSA-Q-2008-2335, EFSA-Q-2008-2336, EFSA-Q-2008-2337, EFSA-Q-2008-2443, EFSA-Q-2008-2473, EFSA-Q-2008-2668, EFSA-Q-2008-2737, EFSA-Q-2008-2738, adopted on 08 April 2011.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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### **Improvement of cognitive function**

The claimed effects are “physical and mental stimulation (hydration and caffeine)”, “mental and cognitive health”, “cognitive function”, “neurological functions”, “physiological antagonistic against caffeine”, and “cognitive performance: focussed attention”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications from Member States, the Panel assumes that the claimed effects refer to improvement of cognitive function. The Panel considers that improvement of cognitive function is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the three human studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of L-theanine on improvement of cognitive function.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and improvement of cognitive function.

### **Alleviation of psychological stress**

The claimed effects are “relaxation” and “neurological functions”. The target population is assumed to be the general population. In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effects refer to alleviation of psychological stress. The Panel considers that alleviation of psychological stress might be a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and alleviation of psychological stress.

### **Maintenance of normal sleep**

The claimed effects are “mental and cognitive health”, and “relaxation”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications from Member States, the Panel assumes that the claimed effects refer to the maintenance of normal sleep. The Panel considers that maintenance of normal sleep is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and maintenance of normal sleep.

### **Reduction of menstrual discomfort**

The claimed effect is “menstrual health”. The target population is assumed to be women with premenstrual syndrome. In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effect refers to reduction of menstrual discomfort. The Panel considers that reduction of menstrual discomfort is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and reduction of menstrual discomfort.

**KEY WORDS**

*Camillia sinensis* (L.) Kuntze, tea, L-theanine, cognitive function, stress, sleep, menstrual discomfort, health claims.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

## **EFSA DISCLAIMER**

See Appendix B

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The foods/food constituents that are the subject of the health claims are *Camellia sinensis* (L.) Kuntze (tea) and L-theanine.

Theanine ( $\gamma$ -glutamylethylamide) is a glutamic acid analogue present mainly in the tea plant (*Camellia sinensis*), although its presence has also been reported in the mushroom *Xerocomus basius*. Theanine comprises 1-2 % of the dry weight of tea leaves. It is synthesised from glutamic acid and ethylamine in tea roots, and accounts for about 50 % of total amino acids in tea (Ekborg-Ott et al., 1997). L-theanine is a well characterised substance which can be measured by established methods.

The plant *Camellia sinensis* (L.) Kuntze is an evergreen shrub of the *Theaceae* family. Tea is an extract of the dried leaves of *Camellia sinensis* (L.) Kuntze, and it is usually prepared by infusing the leaves in hot water. The composition of the tea leaves depends on a variety of factors, including climate, season, horticultural practices, and the type and age of the plant. Many kinds of tea are produced. Teas can be classified into three major types according to the different degrees of fermentation: green (un-fermented), oolong (semi-fermented) and black (fully fermented) (Wang et al., 2000).

The composition of tea drinks greatly depends on the type of leaves used, on the degree of fermentation and on the methods of preparation (Astill et al., 2001; Kaszkin et al., 2004). The degree of fermentation, the production process, and the method for preparing the tea infusion have not been described in relation to the claims.

Green tea contains polyphenolic compounds, which include flavanols, flavandiols, flavonoids and phenolic acids. Most of the polyphenols in green tea are catechins. Epigallo-catechin-3-gallate (EGCG) is the most abundant catechin in green tea. In black teas, the most abundant polyphenols are tannins, mainly theaflavin and thearubigin (Mukhtar and Ahmad, 2000). Tea extracts/infusions also contain variable amounts of potentially active food constituents, such as caffeine or theogallin.

The Panel considers that while *Camellia sinensis* (L.) Kuntze (tea) is not sufficiently characterised in relation to the claimed effects, L-theanine from *Camellia sinensis* (L.) Kuntze (tea) is sufficiently characterised.

<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

<sup>5</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

## **2. Relevance of the claimed effect to human health**

### **2.1. Improvement of cognitive function (ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005)**

The claimed effects are “physical and mental stimulation (hydration and caffeine)”, “mental and cognitive health”, “cognitive function”, “neurological functions”, “physiological antagonistic against caffeine”, and “cognitive performance: focussed attention”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications from Member States, the Panel assumes that the claimed effects refer to improvement of cognitive function.

Cognitive function includes memory, attention (concentration), learning, intelligence and problem solving, which are well defined constructs and which can be measured by validated psychometric cognitive tests.

The Panel considers that improvement of cognitive function is a beneficial physiological effect.

### **2.2. Alleviation of psychological stress (ID 1598, 1601)**

The claimed effects are “relaxation” and “neurological functions”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effects refer to alleviation of psychological stress.

Psychological stress can be measured by established methods.

The Panel considers that alleviation of psychological stress might be a beneficial physiological effect.

### **2.3. Maintenance of normal sleep (ID 1222, 1737, 2004)**

The claimed effects are “mental and cognitive health”, and “relaxation”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications from Member States, the Panel assumes that the claimed effects refer to the maintenance of normal sleep. Normal sleep, including normal sleep onset latency, efficiency, duration and quality, can be measured by validated methods.

The Panel considers that maintenance of normal sleep is a beneficial physiological effect.

### **2.4. Reduction of menstrual discomfort (ID 1599)**

The claimed effect is “menstrual health”. The Panel assumes that the target population is women with premenstrual syndrome.

In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effect refers to reduction of menstrual discomfort, which can be assessed as changes in the severity of symptoms related to the premenstrual syndrome using validated questionnaires.

The Panel considers that reduction of menstrual discomfort is a beneficial physiological effect.



### 3. Scientific substantiation of the claimed effect

The references provided included a report from an authoritative body on the effects of isolated L-theanine given at pharmacological doses, narrative reviews and monographs on the characterisation of the *Camellia sinensis* (L.) Kuntze plant and its byproducts, and a number of narrative reviews about the health effects of L-theanine. These publications did not contain original data which could be used for the scientific substantiation of the claims. A number of the references provided reported either on the effects of food constituents (e.g. caffeine and catechins) other than L-theanine, on the effects of L-theanine in combination with other food constituents (e.g. caffeine), or on health outcomes (e.g. anxiety, mood, brain chemistry, brain ischaemia, theanine bioavailability, theanine toxicity, hydration and cardiovascular health) other than the claimed effects. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

#### 3.1. Improvement of cognitive function (ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005)

One abstract from a conference proceeding was provided which contained insufficient information for a scientific evaluation. Two studies were in Korean and a translation into an EU language was not available to the Panel. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two human intervention studies (Hindmarch et al., 1998; 2000) in healthy volunteers investigated the effects of the consumption of black tea and other beverages on cognition and psychomotor performance using a battery of psychometric tests. The Panel notes that the L-theanine content of the tea used in these studies was not reported. One cross-sectional study examined the association between green tea consumption and cognitive function in 1,003 Japanese subjects aged >70 years (Kuriyama et al., 2006). The Panel notes that the L-theanine intake associated with tea consumption was not reported. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

A study by Kobayashi et al. (1998) assessed outcomes related to brain electrical activity patterns in humans after L-theanine consumption. The Panel notes that brain electrical activity patterns are not established measures of cognitive function. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

A double-blind, cross-over intervention study (Gomez-Ramirez et al., 2007) investigated the effects of L-theanine (250 mg in 200 mL water) vs. water alone (placebo) in healthy male and female volunteers (n=15). Participants received L-theanine or the placebo on two different test days, the order of which was counter balanced across participants. The participants then undertook a standard intersensory attentional cueing task (auditory and visual tasks). The reaction time was significantly longer after consumption of L-theanine than after consumption of placebo ( $p<0.05$ ). There were no other effects of L-theanine on outcomes of cognitive function. The Panel notes that this study does not show a beneficial physiological effect of L-theanine on cognitive outcomes.

Another double-blind, placebo-controlled trial (Rogers et al., 2008) in healthy students (n=48) evaluated the effect on performance of a drink containing L-theanine (200 mg) vs. the same drink without L-theanine (placebo) using a visual probe task. Reaction time on the visual probe task was significantly longer after consumption of L-theanine than after consumption of placebo ( $p<0.046$ ). No other significant differences on cognitive outcomes were observed between the L-theanine and placebo. The Panel notes that this study does not show a beneficial physiological effect of L-theanine on cognitive outcomes.

The references also included a randomised, double-blind, cross-over study (Haskell et al., 2008) which investigated the acute effects of a drink containing L-theanine (250 mg) compared to the same drink without L-theanine (placebo) on cognitive and mood outcomes in 24 healthy students. A

‘tailored’ version of the Cognitive Drug Research battery (CDR Ltd.), a logical reasoning task, a sentence verification task and serial subtraction tasks were used to assess cognitive function. L-theanine significantly impaired performance on the serial sevens subtraction task compared to placebo ( $p < 0.05$ ). No other significant differences on cognitive outcomes were observed between L-theanine and placebo periods. The Panel notes that this study does not show a beneficial physiological effect of L-theanine on cognitive outcomes.

In weighing the evidence, the Panel took into account that the three human studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of L-theanine on improvement of cognitive function.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and improvement of cognitive function.

### **3.2. Alleviation of psychological stress (ID 1598, 1601)**

Among the human studies provided, eight references were published in Japanese or Korean and a translation into an EU language was not available to the Panel. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Among the references provided were conference proceedings for which only the abstracts were available. The Panel notes that insufficient information was provided in these abstracts for a full scientific evaluation of the studies.

Two references investigated the effects of L-theanine consumption on brain electrical responses to cognitive tasks (Dimpfel et al., 2007; Gomez-Ramirez et al., 2007). The Panel notes that changes in brain electrical activity patterns are not considered to be a validated endpoint with respect to alleviation of psychological stress. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

In a randomised, double-blind, placebo-controlled, cross-over (Latin square design) intervention study, 16 healthy volunteers (age range: 18-34 years) received a benzodiazepine anxiolytic (alprazolam, 1 mg), L-theanine (200 mg) or placebo (unspecified) on three different testing days with a minimum wash-out period of seven days (Lu et al., 2004). Measures of anxiety (Beck anxiety inventory (BAI), Bond and Lader visual analogue mood scale (VAMS)) were obtained before the administration of the treatments, and 2.5 h and 5 h thereafter. The tests were undertaken at rest and also under experimentally induced anxiety conditions. The Panel notes that in the absence of direct measures of psychological stress, no conclusions can be drawn from measures of anxiety for the scientific substantiation of a claim on psychological stress. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Another randomised, double-blind, placebo-controlled, cross-over (Latin square design) study examined psychological and physiological responses to stress in 12 healthy male volunteers (age range: 20-25 years) after consumption of L-theanine (200 mg dissolved in 100 mL of water), placebo (water alone), or when receiving no treatment in four test sessions (Kimura et al., 2007). Each experimental session began with a 20 min rest period, followed by a mental arithmetic task for 20 min to induce stress, and then by two rest periods of 10 min. L-theanine was administered either at the beginning of the experiment (test 1) or immediately before the arithmetic task (test 2), whereas placebo was administered only at the beginning of the experiment (test 3). In an additional experimental session (test 4), no treatment was given and a rest period was substituted for the arithmetic task (control). At the end of each test session, subjective stress was measured using a visual analogue scale, and anxiety was evaluated with the state scale of the state-trait anxiety inventory

(STAI). Heart rate (measured continuously), heart rate variability (measured continuously) and saliva-IgA (obtained at the end of each test session) were also assessed. The Panel notes that the measure of psychological stress used in this study was unspecified, and that in the absence of direct measures of psychological stress no conclusions can be drawn from measures of anxiety for the scientific substantiation of a claim on psychological stress. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and alleviation of psychological stress.

### **3.3. Maintenance of normal sleep (ID 1222, 1737, 2004)**

One human study in healthy volunteers (Hindmarch et al., 2000) which investigated the effects of the consumption of black tea on sleep was provided. The Panel notes that the L-theanine content of the tea used in this study was not specified. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and maintenance of normal sleep.

### **3.4. Reduction of menstrual discomfort (ID 1599)**

The references provided included a book chapter and a narrative review which did not contain any original data for the scientific substantiation of the claim. Another research paper reported on the effects of L-theanine consumption on health outcomes (i.e. brain electrophysiological activity) unrelated to premenstrual syndrome. One study was published in Japanese and a translation into an EU language was not available to the Panel. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

An abstract, published in conference proceedings, reported on the effect of L-theanine on the premenstrual syndrome (Terashima and Yokogoshi, 2001). The information provided regarding the study design, methodology and statistical analyses was insufficient for a full scientific evaluation. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and reduction of menstrual discomfort.

## **CONCLUSIONS**

On the basis of the data presented, the Panel concludes that:

- The food, *Camellia sinensis* (L.) Kuntze (tea), which is the subject of the health claims, is not sufficiently characterised in relation to the claimed effects, whereas L-theanine from *Camellia sinensis* (L.) Kuntze (tea) is sufficiently characterised.

### **Improvement of cognitive function (ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005)**

- The claimed effects are “physical and mental stimulation (hydration and caffeine)”, “mental and cognitive health”, “cognitive function”, “neurological functions”, “physiological

antagonistic against caffeine”, and “cognitive performance: focussed attention”. The target population is assumed to be the general population. Improvement of cognitive function is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and improvement of cognitive function.

#### **Alleviation of psychological stress (ID 1598, 1601)**

- The claimed effects are “relaxation” and “neurological functions”. The target population is assumed to be the general population. In the context of the proposed wordings, clarifications from Member States and references provided, it is assumed that the claimed effects refer to alleviation of psychological stress. Alleviation of psychological stress might be a beneficial physiological effect.
- The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and alleviation of psychological stress.

#### **Maintenance of normal sleep (ID 1222, 1737, 2004)**

- The claimed effects are “mental and cognitive health”, and “relaxation”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications from Member States, it is assumed that the claimed effects refer to the maintenance of normal sleep. Maintenance of normal sleep is a beneficial physiological effect.
- The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and maintenance of normal sleep.

#### **Reduction of menstrual discomfort (ID 1599)**

- The claimed effect is “menstrual health”. The target population is assumed to be women with premenstrual syndrome. Reduction of menstrual discomfort is a beneficial physiological effect.
- The Panel concludes that a cause and effect relationship has not been established between the consumption of L-theanine from *Camellia Sinensis* (L.) Kuntze (tea) and reduction of menstrual discomfort.

#### **DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1843, EFSA-Q-2008-1960, EFSA-Q-2008-2334, EFSA-Q-2008-2335, EFSA-Q-2008-2336, EFSA-Q-2008-2337, EFSA-Q-2008-2443, EFSA-Q-2008-2473, EFSA-Q-2008-2668, EFSA-Q-2008-2737, EFSA-Q-2008-2738). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>6</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>7</sup>

Foods are commonly involved in many different functions<sup>8</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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<sup>6</sup> OJ L12, 18/01/2007

<sup>7</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>8</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).



It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### **WORDING OF HEALTH CLAIMS**

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity



consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

## APPENDIX C

Table 1. Main entry health claims related to L-theanine from *Camellia sinensis* (L.) Kuntze (tea), including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1104	Camellia sinensis (Common Name : Tea)	Physical and mental stimulation (hydration and caffeine)	Tea helps refresh body and mind/Tea helps to revive you/Tea helps keeping you alert
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- 200ml (1 cup) of black tea (equivalent to 0.4- 0.5g/serving tea solids)</li> <li>- Blätter, Knospen /Äquivalent von 3 - 6 Tassen Tee oder 45-200 mg L-Theanin pro Tag</li> <li>- No Milk/Sugar added</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1222	Camellia sinensis (Common Name : Tea)	Mental and cognitive health	Supports natural sleep /relaxing /promotes concentration /theanine from thea contributes to soothing effect
	<b>Conditions of use</b> <ul style="list-style-type: none"> <li>- Leaf, bud / The equivalent of 3-6 cups of tea or 45-200 mg of L-theanine per day</li> <li>- At least 30 mg of the green tea extract</li> <li>- Not less than 10 mg of Camellia sinensis leaf extract 5:1 a day</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1598	L-theanine	Relaxation <u>Clarification provided</u> <ul style="list-style-type: none"> <li>- Promotes relaxation/helps to promote relaxation without drowsiness through modulating resting state of brains (in which EEG is in alpha frequency band).- Reduces/helps to reduce stressed out feeling by modulating resting state of brains- Eases nervousness due to common every day overwork and fatigue through modulating resting state of rains (in which EEG is in alpha frequency band which also enhances focused attentional process).- Calming down and relaxing through modulating resting state of brains.- Gently</li> </ul>	<ul style="list-style-type: none"> <li>-help relaxation without drowsiness.</li> <li>-Stress relief.</li> <li>-Physical stress relief.</li> <li>-Relax from fatigue.</li> <li>-Support relation for optimal mental and physical well-being.</li> </ul>

		<p>soothe away the tension (by modulating resting state of brains).- Calmative (through modulating resting state of brains).- Resolving that irritability that ruins your day (by modulating resting state of brains).- Reduces restlessness (by modulating resting state of brains).- Reduces nervous irritability by modulating resting state of brains.- When you're under occasional stress, helps you work relaxed (through modulating resting state of brains). - Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness (should not imply treatment of chronic fatigue or daytime drowsiness as these are symptoms of chronic fatigue syndrome and narcolepsy, respectively) through modulating resting state of brains, in which EEG is in alpha frequency band which also enhances focused attentional process.- Helps learning performance (by enhancing alpha attention effect).- Helps to improve concentration (by enhancing alpha attention effect).- Helps to improve attention (by enhancing alpha attention effect).</p>	
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 100 – 200 mg a day</li> <li>- Food supplement with 100-300mg of L-theanine (Suntheanine) in the daily dose.</li> <li>- Recommended dosage: 50~250 mg JFFA approved for unlimited use in foods with the exception of infant foods. An amino acid from tea, present in the range of 4.30 mg to 24 mg per gram of tea. A cup of tea may contain 13.0 to 75.0 mg of theanine Safety studies such as 28 Day Subacute Toxicity Study, (2,000 mg/kg/day for 28 days) 78 Week Evaluation of Toxicity and Carcinogenicity Acute Toxicity/LD-50 Determination (5,000 mg/kg/day – 7 days) Ames Salmonella/Microsome Plate Test for Mutagenicity 2 week Dietary Range Finding Toxicity Study in Rats (6500 mg/kg/day) 13 week dietary toxicity and toxicokinetic study in rats (4000mg/kg/day), proved safety of L-theanine.</li> <li>- Food supplement with 75-225 mg of theanine and oat shoot extract (equivalent to 400-1200 mg of fresh oat shoot) in the daily dose.</li> </ul>		

ID	Food or Food constituent	Health Relationship	Proposed wording
1599	L-theanine	<p>Menstrual health</p> <p><u>Clarification provided</u></p> <p>MAS (Manifest anxiety scale) based surveys showed that L-theanine relieved the physical and mental stress in several women during their menstrual periods. Promoting the brain alpha waves and attenuating the sympathetic nervous system: Helps to improve physical and psychological symptoms associated with premenstrual syndrome (PMS) Support for normal physical and mental state during premenstrual period Improve aggression and physical stress during premenstrual period. Support painless and stress free menstrual periods. Improve quality of life during menstrual cycle</p>	<p>-help to maintained a calm and relaxed physical and psychological state pre-</p> <p>-support in premenstrual syndrome. Support a normal healthy attitude during menstrual cycle.</p>
		<p><b>Conditions of use</b></p> <p>- 200mg/day</p>	
ID	Food or Food constituent	Health Relationship	Proposed wording
1600	L- theanine	Cognitive function	<p>- Help learning performance.</p> <p>- Help to improve concentration.</p> <p>- Help to improve attention.</p> <p>- Sports support</p>
			<p><b>Conditions of use</b></p> <p>- 200 mg</p>
ID	Food or Food constituent	Health Relationship	Proposed wording
1601	L-theanine	<p>Neurological functions</p> <p><u>Clarification provided</u></p> <p>Helps the brain to protect from neuro toxins: Helps to attenuate sympathetic nervous activation to induce anti-stress effects Help the brain to protect from neuron damage L-theanine has antagonist against Caffeine</p>	<p>- Neuroprotective.</p> <p>- Brain support</p>

		induced convulsion and excitation and Glutamate induced apoptosis and neuron damage. L-theanine protects against ischemic refusion induced neuronal death. L-theanine improves the cognitive function. Important for neuro-protection and normal brain function.	
	<b>Conditions of use</b> - Up to 1 mg/kg BW in animal studies		
ID	Food or Food constituent	Health Relationship	Proposed wording
1707	Teanine	Cognitive function <u>Clarification provided</u> Neuromuscular system	It helps relax status without reducing the “alert status”; It helps against nervous tension
	<b>Conditions of use</b> - 12,5 mg/sachet		
ID	Food or Food constituent	Health Relationship	Proposed wording
1737	L-Theanine	Relaxation <u>Clarification provided</u> Helps promote the onset of sleep. Reduces psychological and physiological stress responses via the inhibition of cortical neuron excitation and increased alpha-wave brain activity.	helps to maintain an optimal relaxation; helps to support the relaxation ; helps to maintain a healthy sleep
	<b>Conditions of use</b> - 200 mg - 200 mg/day		
ID	Food or Food constituent	Health Relationship	Proposed wording
1935	L- theanine	Physiological antagonistic against caffeine <u>Clarifications provided</u> Focus/Attention: L-theanine reduces the convulsions and excitation induced by caffeine (antagonistic effect). Improves the mood, focus and cognitive functions. Reduced the reaction time in visual probe task, enhanced hit rate, target discriminability,	Caffeine antagonist

		attention and ignoring distraction.	
	<b>Conditions of use</b> - 5-10 micro mole/kg		
ID	Food or Food constituent	Health Relationship	Proposed wording
2004	Camellia sinensis (Common Name : Tea)	Mental and cognitive health	Supports natural sleep /relaxing /promotes concentration /theanine from thea contributes to soothing effect
	<b>Conditions of use</b> - Leaf, bud / The equivalent of 3-6 cups of tea or 45-200 mg of L-theanine per day - Liście, pąk/ równowartość 3 do 6 szklanek herbaty lub 45-200 mg L-teaniny na dzień		
ID	Food or Food constituent	Health Relationship	Proposed wording
2005	Camellia sinensis (Common Name: Tea)	Cognitive Performance: Focussed attention	Tea helps you focus/ concentrate/ be less distracted/ helps you to be sharp/ helps you to be alert - Tea contains theanine/ Theanine stimulates alpha brainwaves which are associated with a relaxed but alert mental state;  Theanine helps relax your mind/helps you to be relaxed; promotes a restful, relaxed state; calms and clears the mind
	<b>Conditions of use</b> - 2 to 3 cups of black tea (providing > 45 mg L-theanine) - 2 do 3 szklanek czarnej herbaty (dostarczających >45 mg L-teaniny)		

**GLOSSARY AND ABBREVIATIONS**

BAI	Beck anxiety inventory
EGCG	Epigallo-catechin-3-gallate
STAI	State-trait anxiety inventory
VAMS	Visual analogue mood scale